**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF MISSOURI**
**EASTERN DIVISION**

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| **RICHARD HEINZ,** | ) | **Civil Action No.:** 4:16-cv-1587 |
| | ) | |
| **Plaintiff,** | ) | |
| | ) | |
| **v.** | ) | **COMPLAINT AND JURY DEMAND** |
| | ) | |
| | ) | |
| **ATRIUM MEDICAL CORPORATION, MAQUET CARDIOVASCULAR, LLC d/b/a MAQUET MEDICAL SYSTEMS USA; GETINGE GROUP AB, GETINGE USA, INC. and DOES 1-20,** | ) | |
| | ) | |
| **Defendants.** | ) | |

Plaintiff, by and through his undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state the following:

1. This is a device tort action brought on behalf of the above named Plaintiff arising out of the failure of Defendants' hernia mesh product. As a result, Plaintiff RICHARD HEINZ suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

## I. PARTIES

2. Plaintiff Richard Heinz ("Plaintiff") is a citizen and resident of Missouri and the United States.

3. Defendant Atrium Medical Corporation ("Atrium") is a corporation organized under the laws of Delaware, with its corporate headquarter and principal place of business located in Merrimack, New Hampshire. Atrium Medical Corporation identifies its registered agent for service of process as CT Corporation System, located at 9 Capitol Street in Concord, New Hampshire. Atrium is a pharmaceutical and medical device company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including C-Qur mesh.

4. Defendant Maquet Cardiovascular, LLC ("Maquet CV") is a corporation organized under the laws of Delaware, with its principal place of business at 45 Barbour Pond Drive, Wayne, New Jersey 07470. Maquet CV also conducts business under the name Maquet Medical Systems USA, although such entity name is not registered in the States of Delaware or New Jersey. Maquet CV is a pharmaceutical and medical device company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including C-Qur mesh.

5. Defendant Getinge Group AB ("Getinge") is a Swedish corporation doing business in the United States. Getinge is a pharmaceutical and medical device company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including C-Qur mesh. Getinge is headquartered at Theres Svenssons gate 7, P.O. Box 8861 SE-402 72 Göteborg, Sweden. Getinge and its subsidiary, Maquet, acquired Atrium and all of Atrium's liabilities in the fourth quarter of 2011. The US headquarters of Getinge is located at 45 Barbour Pond Drive, Wayne, New Jersey 07470.

6. Defendant Getinge USA, INC. ("Getinge USA") is a corporation organized under the laws of Delaware, with its principle place of business at 1777 East Henrietta Road, Rochester, New York. Getinge USA is a pharmaceutical company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including C-Qur mesh. Getinge USA is a subsidiary of Getinge.

7. The true names and capacities, whether individual, corporate, associate or otherwise, of defendants DOES 1 through 20, are unknown to Plaintiff who therefore sues these defendants by such fictitious names. Plaintiff will amend this Complaint when the true names and capacities of these fictitiously named defendants are ascertained. Plaintiff is informed and believes, and thereon alleges, that each fictitiously named defendant, whether as a supplier, manufacturer, distributor, researcher, analyst, manager, supervisor, marketer, seller, parent company, or subsidiary, is responsible, strictly, negligently, in warranty, fraudulently, or otherwise, for the occurrences alleged in this Complaint, and caused the injuries and damages sustained by Plaintiff as herein alleged.

8. At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed Hernia Mesh Products in the stream of commerce, including the C-Qur mesh that is at issue in this lawsuit.

9. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

10. At all relevant times, each of the Defendants, was and still is a corporation authorized to do business in the State of Missouri.

11. At all times hereinafter mentioned, upon information and belief, each of the Defendants, was and still is a business entity actually doing business in the State of Missouri.

12. Defendants share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Defendants."

13. At all times hereinafter mentioned, each of the Defendants were, and are currently, engaged in the business of designing, manufacturing, advertising, marketing, and selling Hernia Mesh Products including the C-Qur Mesh Family (referred to herein, at times as "C-Qur Mesh" or "Hernia Mesh Product"), and in pursuance of this business, transacts business within the State of Missouri and contracts to provide goods and services in the State of Missouri.

14. At all times hereinafter mentioned, upon information and belief, Defendants committed tortious acts inside and outside the State of Missouri, which caused injury to Plaintiff inside the State of Missouri.

15. At all times hereinafter mentioned, upon information and belief, Defendants expect or should reasonably expect its acts to have consequences in the State of Missouri, and derives substantial revenue from interstate or international commerce.

## II. VENUE AND JURISDICTION

16. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. §1332(a)-(c).

17. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

18. Venue is proper in this Court pursuant to 28 28 U.S.C. §1332(a)-(c) by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendants' products are sold to and consumed by individuals in the State of Missouri, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

19. Defendants have and continue to conduct substantial business in the State of Missouri and in this District, distribute Hernia Mesh Products in this District, receive substantial compensation and profits from sales of Hernia Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

20. Defendants conducted business in the State of Missouri through sales representatives conducting business in the State of Missouri and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, and/or through third parties or related entities, Hernia Mesh Products in Missouri.

21. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Missouri, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

## III. DEFENDANTS' HERNIA MESH PRODUCTS

22. In or about 1993, Defendants began to market and sell surgical mesh for the treatment of multiple medical conditions, primarily hernia repair.

23. Specifically, Atrium sought and secured 510(k) clearance on the following medical devices indicated and/or sold for hernia repair: ProLite Mesh (K930669) on December 16, 1993, ProLite Ultra Mesh (K002093) on July 24, 2000, C-Qur Mesh (K050311) on March 31, 2006, Prolite Ultra S Mesh (K070192) on March 8, 2007, C-Qur Lite V-Patch (K080688) on April 16, 2008, C-Qur Edge V-Patch (K080691) on April 16, 2008, Prolite S Mesh (K082748) on January 14, 2009, C-Qur V-Patch (K090909) on June 4, 2009, C-Qur Ovt (K100076) on January 26, 2010, Centrilfx (K110110) on February 15, 2011, C-Qur Rpm (K121070) on April 26, 2012, Prolite, Prolite Ultra, Proloo (K151437) on August 27, 2015, and C-Qur, C-Qur Fx, C-Qur Tachshield, C-Qur V-Patch, C-Qur CentriFX, and C-Qur Mosiac (K151386) on October 22, 2015.

24. Defendants' Hernia Mesh Products were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

25. Defendants' Products contain polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes and immune response in a large subset of the population receiving Defendants' Products. This immune response promotes degradation of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

26. Defendants' statements made to the FDA regarding these Medical Devices inadequately relied on predicate devices and not clinical testing or other design verification or testing. These statements induced the Plaintiff into relying upon the Defendants' judgment.

27. Upon information and belief, Defendants' numerous suppliers of various forms of polypropylene warn on their United States Material Safety Data Sheet ("MSDS") that it is prohibited to permanently implant polypropylene into the human body.

28. Defendants' polypropylene based Hernia Mesh Products are designed, intended, and utilized for permanent implantation into the human body.

29. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the known severe and life-threatening risk associated with polypropylene.

30. Upon information and belief, Defendants' use adulterated polypropylene in their Hernia Mesh Products.

31. Defendants' failed to warn or notify doctors, regulatory agencies, and consumers of the Defendants' use of adulterated polypropylene in their Hernia Mesh Products.

32. Defendants' C-Qur Mesh utilizes a blend of Omega 3 Fatty Acid Fish Oil ("O3FA") to form a barrier coating on its C-Qur Mesh.

33. The O3FA is derived from fish. Fish derivatives are considered to be commonly allergenic and immunogenic. If various remnants of the fish – such as proteins, genetic material, and/or adjuvant compounds – remain in the O3FA coating, an immune response can occur, causing complications including but not limited to pain, graft rejection, graft migration, organ damage, complex seroma, delayed wound closure, infection, sepsis, and death.

34. Proteins are not very soluble in oils; however, non-soluble proteins are still able to be present in the oil as particulate matter.

35. Upon information and belief, Defendants' failed to adequately test, inspect, and/or verify that each supplied batch of O3FA was free from proteins and genetic material.

36. Upon information and belief, Defendants' utilized adulterated O3FA from sources other than those reported to the FDA.

37. Prior to the C-Qur mesh entering the stream of commerce, The United States Food and Drug Administration ("FDA") and other governmental regulatory agencies worldwide expressed their stark concerns to Defendants regarding severe, life-threatening allergic and immunogenic reactions to the O3FA coating when implanted in humans.

38. Upon receiving reports from surgeons and physicians of apparent allergic reactions to the C-Qur Mesh, Defendants not only failed to notify the FDA, but misled physicians about the ability and tendency of O3FA to cause allergic reactions in patients implanted with a C-Qur Mesh and attempted to convince the physicians of alternate causes. Defendants' intentionally, or at very least, recklessly disregarded human life by lying to physicians about the possible causes of the allergic reaction, resulting in significantly more severe injuries in those already implanted with the C-Qur Mesh, and more patients nationwide being implanted with the C-Qur Mesh.

39. Upon information and belief, Defendants' changed the way in which they handled and/or applied the O3FA coating to the C-Qur Mesh. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

40. Upon information and belief, Defendants' utilized non-conforming goods in the production of the C-Qur Mesh, including accepting goods without the required documentation to verify the source, quality, authenticity, or chain of custody of the goods.

41. Upon information and belief, the O3FA component of Defendants' C-Qur Mesh is cytotoxic and not biocompatible, resulting in complications such as delayed wound healing, inflammation, foreign body response, rejection, and death.

42. Upon information and belief, Defendants had actual knowledge of the cytotoxic properties of the O3FA component of the C-Qur Mesh prior to introducing it into the stream of commerce.

43. Defendants failed to adequately test the effects of the known cytotoxicity of the C-Qur Mesh in animals and humans, both before and after the product entered the stream of commerce.

44. Defendants' failed to warn or notify doctor, regulatory agencies, and consumers of the cytotoxicity of the C-Qur Mesh.

45. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the C-Qur Mesh. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. C-Qur Mesh implanted with spores will result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the C-Qur Mesh.

46. Moisture and high humidity levels are contraindicated for the C-Qur Mesh, as it will result in the O3FA coating peeling off the polypropylene and/or sticking to the packaging.

47. Defendants' use of ETO on the C-Qur Mesh results in either:

A. High infection rates due to inadequate moisture during the ETO cycle; or

B. O3FA coating peeling off the polypropylene due to moisture.

48. Defendants failed to warn or instruct distributors and facilities of critical environmental guidelines, such as relative humidity or temperature during transportation and/or storage of the C-Qur Mesh. The environmental guidelines for the C-Qur Mesh are unique to the C-Qur Mesh and are not necessary for other similar or competing hernia mesh products. Excess temperature and/or humidity result in the C-Qur Mesh degrading and transforming into an even more dangerous product.

49. Defendants failed to conduct adequate testing to determine the proper environmental guidelines for storage and transportation of the C-Qur Mesh prior to introducing it into the stream of commerce.

50. ETO is ineffective at sterilizing the C-Qur Mesh due the O3FA coating, multiple layers of the mesh, and mated surfaces of the C-Qur Mesh.

51. Defendants' changed the process of their ETO sterilization cycle without performing adequate testing or verification of sterility, or other effects the changes might have had on the product. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

52. Upon information and belief, Defendants utilized a package that allowed

humidity levels to fluctuate to unacceptably high levels within the package.

53. Upon information and belief, Defendants utilized a packaging material that promoted the O3FA coating to adhere to the packaging of the C-Qur Mesh.

54. Upon information and belief, Defendants manufactured the C-Qur Mesh in a way that promoted that O3FA coating to adhere to the packaging of the C-Qur Mesh.

55. Defendants failed to properly warn physicians, regulatory agencies, and consumers of the risk associated with the O3FA coating adhering to the package. Defendants' assured physicians and regulatory agencies that the C-Qur Mesh was still fit for human implantation, even if some or all of the O3FA coating had been pulled away.

56. Once the O3FA coating has started or shown propensity to detach from the polypropylene, it is much more likely that the O3FA coating will detach from the polypropylene once implanted. If the O3FA coating detaches once implanted, it can float in the body or ball up, causing an even more intense foreign body reaction, resulting in rejection and other complications the C-Qur Mesh. Detachment of the O3FA coating also greatly increases the risk of the C-Qur Mesh adhering to the patients underlying organs, resulting in significantly more difficult and complex surgeries to remove the mesh. Due to the C-Qur Mesh adhering to the underlying organs, patients experience significant, life-changing injuries, prolonged hospital stays, and even death.

57. Defendants were and are currently aware of the life-threatening complications associated with the O3FA coating peeling off inside of patients.

58. Defendants encouraged physicians to implant C-Qur Mesh in which the O3FA coating had peeled away from the polypropylene and was stuck to the packaging.

59. Defendants' encouragement of physicians to implant C-Qur Mesh in which the O3FA coating had adhered to the packaging and was no longer present on the polypropylene was an intentional, or at very least, a reckless disregard of human life.

60. Defendants changed the way in which the C-Qur Mesh is packaged. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

61. Upon information and belief, at relevant times, Defendant modified the processing temperature and processing speed of one or more steps in the manufacturing process. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety. The FDA was not notified of the deviation.

62. Upon information and belief, Defendants adjusted the threshold for reporting and recalling the C-Qur Mesh due to nonconformities and adverse event reports when the threshold was met, resulting in a large number of injurious events that were deemed by the Defendants to be "acceptable" and went unreported as a result and unrecalled.

63. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the C-Qur Mesh.

64. Upon information and belief, Defendants paid researchers, doctors, clinicians, study designers, authors, and/or scientist to study the effectiveness of the C-Qur Mesh, but did not disclose these relationships in the study itself or to any regulatory body.

65. Upon information and belief, Defendants' paid doctors, surgeons, physicians, and/or clinicians to promote the C-Qur Mesh, but did not readily disclose this information.

66. Defendants' failed to properly investigate and disclose adverse event reports to the FDA and other regulatory agencies worldwide.

67. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

68. Defendants failed to employ an adequate number of staff to receive, process, investigate, document, and report adverse events.

69. Defendants "stealth recalled" multiple types of C-Qur Mesh that were experiencing high levels of adverse events, by simply halting production of multiple types of C-Qur Mesh without notifying physicians, regulatory agencies, or consumers of the recall or high levels of adverse events.

70. Defendants failed to implement adequate procedures and policies to detect the presence of foreign materials in or on the C-Qur Mesh.

71. Defendants failed to implement adequate procedures and policies to prevent C-Qur Mesh with known foreign materials from entering the stream of commerce.

72. Defendants failed to design a method or process that ensures conformity in the amount of O3FA applied to each type of C-Qur Mesh.

73. Defendants failed to warn or instruct physicians on the proper and/or contraindicated methods of securing and/or implanting the C-Qur Mesh. Defendants blamed physicians' methods of implantation and securing the C-Qur Mesh when complications known by

the Defendants to be caused by a defect in the C-Qur Mesh were reported by physicians. This resulted in fewer adverse event reports to the FDA and more C-Qur Mesh implants nationwide.

74. Defendants marketed the C-Qur Mesh to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants' did not undergo pre-market approval for the C-Qur Mesh and are therefore prohibited by the FDA from asserting superiority claims. Defendants have made claims that the C-Qur Mesh is superior in a variety of ways, but have never conducted a single clinical study on the C-Qur Mesh implanted in humans. Defendants' deception through false advertising resulted in more physicians utilizing the C-Qur Mesh.

75. Defendants signed a national contract with Premier Inc. ("Premier"), a group purchasing organization, on August 10, 2010. Premier supplies medical devices in bulk to member hospitals at a reduced cost. Defendants' contract with Premier greatly increased the nationwide demand for the C-Qur Mesh. Defendants changed numerous aspects of the manufacturing process of the C-Qur Mesh, before and after the contract with Premier, in order to increase production and decrease cost.

76. Defendants marketed and sold the C-QUR Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, and include the provision of valuable benefits to health care providers. Also utilized were documents, patient brochures, and websites.

77. For years the Defendants have been notified and warned about the widespread catastrophic complications associated with the C-Qur Mesh by leading hernia repair specialists, surgeons, hospitals, patients, regulatory agencies, internal consultants, and employees. However, not a single C-Qur Mesh has been recalled from the market. Defendants have misrepresented the efficacy and safety of the C-Qur Mesh, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

78. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' C-Qur Meshes were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a results, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the defendants' C-Qur Meshes were and are safe and effective, leading to the prescription for and implantation of the C-Qur Mesh into the Plaintiff.

79. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' C-Qur Mesh.

80. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' C-Qur Mesh; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' C-Qur Mesh.

81. Feasible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at all times relevant as compared to the Defendants' C-Qur Mesh.

82. The Defendants' C-Qur Meshes were at all times utilized and implanted in a manner foreseeable to the Defendants.

83. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' C-Qur Mesh, and thus increase the sales of the C-Qur Mesh, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

84. The C-Qur Mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

## IV. FACTUAL BACKGROUND

85. On April 18, 2012, Plaintiff was seen at Walls Hospital for open repair of incisional hernia. A 15cm x 7.5cm piece of C-Qur TacShield mesh was used to repair this defect.

86. Defendant, manufactured, sold, and/or distributed the C-QUR Mesh Products to Plaintiff, through his doctors, to be used for treatment of hernia repair.

87. In or around June of 2014, Plaintiff began to experience abdominal pain at the site of the implantation of Defendants' C-Qur mesh as well as recurrence of the incisional hernia.

88. On August 14, 2014, Plaintiff saw Dr. Benjamin Cullen regarding his symptoms. Plaintiff was informed that he was suffering from mesh contracture, graft migration, and adhesions of the C-Qur mesh to the small bowel. Plaintiff was further informed that the

integration of the mesh into the viscera was of such a degree as to make the condition inoperable. Dr. Cullen provided Plaintiff with symptomatic triggers for calling 9-1-1 and/or reporting to the nearest emergency room.

89. In the intervening time, Plaintiff has suffered and continues to suffer severe abdominal pain, digestive problems, and infections caused by the failed C-Qur mesh as well as a continually growing abdominal mass.

90. The C-Qur Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the mesh.

91. Other than any degradation caused by faulty design, manufacturing, or faulty packaging**,** the C-QUR Mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

92. Plaintiff and his physicians foreseeably used and implanted the C-QUR Mesh Products, and did not misuse, or alter the Products in an unforeseeable manner.

93. Defendants advertised, promoted, marketed, sold, and distributed the C-QUR Mesh Products as a safe medical device when Defendant knew or should have known the C-QUR Mesh Products were not safe for their intended purposes and that the mesh products could cause serious medical problems.

94. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

95. In reliance on Defendants' representations, Plaintiff's doctor was induced to, and did use the C-Qur Mesh.

96. As a result of having the C-Qur Mesh implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

97. Defendants' C-Qur Meshes have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive or open surgical techniques for the treatment of medical conditions, primarily hernia repair and soft tissue repair, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing hernia mesh products.

98. The Defendants have marketed and sold the Defendants' C-Qur Meshes to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

99. The injuries, conditions, and complications suffered due to Defendants' C-Qur Meshes include but are not limited to foreign body reaction, rashes, infection, adhesions, organ perforation, inflammation, fistula, mesh erosion, scar tissue, blood loss, neuropathic and other acute and chronic nerve damage and pain, abdominal pain, nausea, vomiting, kidney failure, and

in many cases the patients have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove the C-Qur Mesh, operations to attempt to repair abdominal organs, tissue, and nerve damage, the use of narcotics for pain control and other medications, and repeat operations to remove various tissues that are contaminated with the C-Qur Mesh.

100. Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of his injuries including but not limited to the defective design and/or manufacturing the C-Qur Mesh implanted inside of him until a date within the applicable statute of limitations.

**COUNT I**
**NEGLIGENCE**

101. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

102. At all relevant times, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' C-Qur Mesh, and recruitment and training of physicians to implant the C-Qur Mesh.

103. Defendants breached their duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the C-Qur Mesh.

104. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the C-Qur Mesh, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

105. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT II**
**STRICT LIABILITY – DESIGN DEFECT**

106. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

107. At the time each implanting surgeon implanted the mesh product in Plaintiff, Defendant was engaged in the business of selling said product.

108. The C-Qur Mesh was defectively designed when sold.

109. The C-Qur Mesh was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use.

110. The C-Qur Mesh reached Plaintiff's implanting surgeon and was implanted in Plaintiff without substantial change in the condition in which it was sold.

111. The C-Qur Mesh failed to perform as safely as an ordinary consumer would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the mesh product outweigh the benefits.

112. The defective and unreasonably dangerous condition of the C-Qur Mesh was the proximate cause of the damages and injuries to Plaintiff.

113. As a direct and proximate result of the C-Qur Mesh's aforementioned design defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

114. Defendant is strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## COUNT III
## STRICT LIABILITY – MANUFACTURING DEFECT

115. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

116. At the time Plaintiff's doctor implanted the C-Qur Mesh in his body, Defendant was engaged in the business of selling said product.

117. The C-Qur Mesh was unreasonably dangerous to the user, Plaintiff.

118. The C-Qur Mesh was expected to reach and did reach the implanting surgeon and Plaintiff without substantial change in the condition in which it was sold.

119. The C-Qur Mesh which was implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

120. The defective and unreasonably dangerous condition of the mesh product was a proximate cause of damages and injuries to Plaintiff.

121. As a direct and proximate result of the C-Qur Mesh's aforementioned defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

122. Defendant is strictly liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT IV**
**STRICT LIABILITY – FAILURE TO WARN**

123. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

124. The Defendants failed to properly and adequately warn and instruct the Plaintiff and his health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' C-Qur Mesh.

125. The Defendants failed to properly and adequately warn and instruct the Plaintiff and his health care providers as to the risks and benefits of the Defendants' C-Qur Mesh, given the Plaintiff's conditions and need for information.

126. The Defendants failed to properly and adequately warn and instruct the Plaintiff

and his health care providers with regard to the inadequate research and testing of the C-Qur Mesh, and the complete lack of a safe, effective procedure for removal of the C-Qur Mesh.

127. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' C-Qur Mesh, understating the risks and exaggerating the benefits in order to advance their own financial interest, with wanton and willful disregard for the rights and health of the Plaintiff.

128. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the C-Qur Mesh, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

129. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiff demands judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

## COUNT V
## BREACH OF EXPRESS WARRANTY

130. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

131. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' C-Qur Mesh.

132. At all relevant times, Defendants intended that the Defendants' C-Qur Mesh be

used in the manner than Plaintiff in fact used them and Defendants expressly warranted that each C-Qur Mesh and its component parts was safe and fit for use by consumers, that it was merchantable quality, that is side effects were minimal and comparable to other hernia mesh, and that it was adequately tested and fit for its intended use.

133. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the C-Qur Mesh; which is to say that Plaintiff was a foreseeable user of the Defendants' C-Qur Mesh.

134. Plaintiff and/or his implanting physician were at all relevant times in privity with Defendants.

135. The Defendants C-Qur Mesh were expected to reach and did in fact reach consumers, including Plaintiff and his implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

136. Defendants breached various express warranties with respect to the C-Qur Mesh including the following particulars:

A. Defendants represented to Plaintiff and his physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' C-Qur Meshes were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the C-Qur Mesh;

B. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Meshes were safe, and/or safer than other

alternative procedures and devices and fraudulently concealed information, which demonstrated that the C-Qur Meshes were not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Meshes were more efficacious than other alternative procedures and/or devices, and fraudulently concealed information, regarding the true efficacy of the C-Qur Mesh.

137. In reliance upon Defendants' express warranty, Plaintiff individually and/or by and through his physician, was implanted with the Defendants' C-Qur Mesh as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

138. At the time of making such express warranties, Defendants knew or should have known that the Defendants' C-Qur Meshes do not conform to these express representations because the defendants' C-Qur Meshes were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendant's C-Qur Meshes unreasonably unsafe for their intended purpose.

139. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' C-Qur Mesh.

140. Defendants breached their express warranties to Plaintiff in that the Defendants' C-Qur Meshes were not of merchantable quality, safe and fit for their intended uses, nor were

they adequately tested.

141. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT VI**
**BREACH OF IMPLIED WARRANTY**

142. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

143. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' C-Qur Mesh.

144. At all relevant times, Defendants intended that the Defendants' C-Qur Meshes be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendants impliedly warranted each C-Qur Mesh and its component parts to be of merchantable quality, safe and fit for such use, and was not adequately tested.

145. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' C-Qur Mesh in the manner directed by the instructions for use;

which is to say that Plaintiff was a foreseeable user of the Defendants' C-Qur Mesh.

146. Plaintiff and/or Plaintiff's physicians were at all relevant times in privity with Defendants.

147. The Defendants' C-Qur Meshes were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

148. Defendants breached various implied warranties with respect to the C-Qur Mesh including the following particulars:

A. Defendants represented to Plaintiff and his physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' C-Qur Meshes were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the C-Qur Mesh;

B. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Meshes were safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the C-Qur Meshes were not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Meshes were more efficacious than other alternative procedures and/or devices, and fraudulently concealed information, regarding

the true efficacy of the C-Qur Mesh.

149. In reliance upon Defendants' implied warranty, Plaintiff individually and/or by and through his physician, used the C-Qur Mesh as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

150. Defendants breached their implied warranty to Plaintiff in that the Defendants' C-Qur Meshes were not merchantable quality, safe and fit for their intended use, or adequately tested.

151. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## COUNT VII
## VIOLATION OF CONSUMER PROTECTION LAWS

152. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

153. Plaintiff purchased and used the Defendants' C-Qur Mesh primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the

consumer protection laws.

154. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' C-Qur Mesh, and would not have incurred related medical cost and injury.

155. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the C-Qur Mesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

156. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a.) Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have.

b.) Advertising goods or services with the intent not to sell them as advertised; and,

c.) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

157. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' C-Qur Meshes. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' C-Qur Meshes.

158. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' C-Qur Meshes.

159. Had Defendants no engaged in the deceptive conduct described above, Plaintiff would not have purchases and/or paid for the C-Qur Mesh, and would not have incurred related medical cost.

160. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

161. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statues, as listed below.

162. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

- 15 U.S.C. §§ 2301-2312 (1982)
- Missouri Merchandising Practices Act (RSMo §407.010 *et seq*.)

163. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

164. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' C-Qur Meshes were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in

marketing and promotional materials.

165. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

166. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' C-Qur Mesh and failed to take any action to cure such defective and dangerous conditions.

167. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

168. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

169. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages

170. As a direct and proximate result of Defendants' violations of the states; consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems just and proper.

**COUNT VIII**
**GROSS NEGLIGENCE**

171. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

172. The wrongs done by defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

173. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance

174. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

175. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately

caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT IX**
**UNJUST ENRICHMENT**

176. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

177. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' C-Qur Mesh.

178. Plaintiff paid for the Defendants' C-Qur Mesh for the purpose of treatment for hernia repair and/or a soft tissue injury or other similar condition.

179. Defendants have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the Defendants' C-Qur Mesh.

180. Plaintiff has not received the safe and effective medical device for which Plaintiff paid.

181. It would be inequitable for Defendants to keep this money, because Plaintiff did not in fact receive a safe and effective medical device.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,

individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT X**
**NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

182. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

183. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' C-Qur Mesh to Plaintiff.

184. Defendants carelessly and negligently concealed the harmful effects of the Defendants' C-Qur Mesh from Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

185. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the C-Qur Mesh to Plaintiff individually and/or Plaintiff's physician on multiple occasions and continue to do so to this day.

186. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the C-Qur Mesh sold and distributed by Defendants.

187. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the C-Qur Mesh to Plaintiff individually and/or Plaintiff's physician after Plaintiff sustained emotional distress, severe physical injuries, and

economic loss.

188. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the C-Qur Mesh to Plaintiff individually and/or Plaintiff's physician knowing that doing so would cause the Plaintiff to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

189. As a proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT XI**
**NEGLIGENT MISREPRESENATION**

190. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

191. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the C-Qur Mesh had not been adequately tested and found to be safe and effective for the treatment of hernia or soft tissue repair. The representations made by Defendants, in fact, were false.

192. Defendants failed to exercise ordinary care in the representations concerning the C-Qur Mesh while they were involved in their manufacture, sale, testing, quality, assurance,

quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the C-Qur Meshes high risk of unreasonable and dangerous adverse side effects.

193. Defendants breached their duty in representing that the Defendants' C-Qur Meshes have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

194. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the C-Qur Mesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

195. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT XII**
**NEGLIGENCE PER SE**

196. Plaintiff realleges and incorporates by reference every allegation of this Complaints if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

21 U.S.C. § 351(f)

197. Defendants' marketed, promoted, and/or sold their C-Qur Mesh to physicians, Plaintiff, and the public at large as a "Barrier" mesh.

198. The term "Barrier" is a word of art used for adhesion barriers that reduce adhesions between tissues. To be a "Barrier" medical device or use the term "Barrier," the medical device must be a Class III device and must undergo Pre-Market Approval.

199. Defendants' refused to undergo the necessary safety testing and pre-clinical trials required for Pre-Market Approval.

200. Defendants' violated 21 U.S.C. § 351(f) by not obtaining Pre-Market Approval and marketing, promoting, and/or selling the Defendants' C-Qur Mesh as being a "Barrier" mesh and reducing adhesions between tissues.

201. 21 U.S.C. § 351(f) mandates safety testing and pre-clinical trials to protect the general public who have a medical device implanted.

202. Plaintiff is a member of the general public who had a medical device implanted, and therefore is among the class of people the regulation is meant to protect.

203. Plaintiff would not have been implanted with the C-Qur Mesh had the C-Qur Mesh undergone safety testing, pre-clinical trials, and Pre-Market Approval.

204. Plaintiff and/or Plaintiff's physician would not have selected the C-Qur Mesh had

the C-Qur Mesh not been marketed and promoted as a "Barrier" mesh that was more effective at reducing adhesions between tissues.

205. As a direct and proximate result of the Defendants' violation of 21 U.S.C. §351(f), Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

21 U.S.C. §360j(f), 21 C.F.R. Part 820, 21 U.S.C. §331(a),(k)

206. A device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the Quality Systems (QS) regulation for devices, 21 C.F.R Part 820. A device that has been manufactured, packed, stored, or installed in violation of the QS requirement is deemed to be adulterated. 21 U.S.C. § 351(h).

207. The introduction or delivery for introduction into interstate commerce of adulterated or misbranded device is a violation of the Act, 21 U.S.C. § 331(a).

208. Engaging in an act that causes the adulteration or misbranding of a device while it is held for sale after shipment of one or more of its component parts in interstate commerce is a violation of the Act, 21 U.S.C. §331(k).

209. Each of the aforementioned regulations are intended to protect the general public from being implanted with adulterated medical devices.

210. Plaintiff is a member of the general public and was implanted with an adulterated medical device, and therefore is among the class of people the regulation is meant to protect.

211. Defendants' violated 21 U.S.C. §360j(f), 21 C.F.R. Part 820, 21 U.S.C. §331(a) and (k) by adulterating the C-Qur Mesh or the components of the C-Qur Mesh and then introducing the adulterated products into the stream of commerce, and did acts that caused further adulteration or misbranding of the C-Qur Mesh once it was in the stream of commerce.

212. Plaintiff would not have been injured and/or his injuries would not have been as severe had the Defendants' not violated 21 U.S.C. §360j(f), 21 C.F.R. Part 820, 21 U.S.C. §331(a) and (k) and introduced an adulterated medical device into the stream of commerce.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

21 U.S.C. § 331(e)

213. The failure to establish or maintain certain records, or make certain reports, with respect to medical devices, is a violation of the Act, 21 U.S.C. § 331(e), as required by 21 U.S.C. §360i

214. 21 U.S.C. § 331(e) is intended to facilitate the detection of defective medical devices, so that such defective devices can be pulled from the market to prevent the general public from being injured due to a defective medical device.

215. Plaintiff is a member of the general public and was injured by a defective medical device that should have been pulled from the market.

216. Had Defendants' not violated 21 U.S.C. § 331(e), the C-Qur Mesh would have been recalled, or at very least had additional warnings.

217. Plaintiff would not have been implanted with the C-Qur Mesh had the C-Qur Mesh been recalled or had additional warnings.

218. As a direct and proximate result of the Defendants' violation of 21 U.S.C. §331(e), Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

21 C.F.R. § 806.10(a)(1)

219. Failure to report in writing to FDA a correction, removal, and/or discontinuation of a device conducted to reduce a risk to health posed by the device, in violation of 21 C.F.R. § 806.01(a)(1).

220. 21 C.F.R. § 806.01(a)(1) is intended to alert the FDA of a defective and dangerous medical device that is in the stream of commerce, so that the FDA can ensure that the general public and physicians are aware of and can avoid the dangerous medical device on the market.

221. Plaintiff is a member of the general public who was implanted with a dangerous medical device that had previously undergone correction, removal, and/or discontinuation

222. Defendants violated 21 C.F.R. § 806.01(a)(1) by correcting, removing, and/or

discontinuing multiple types of the C-Qur Mesh without reporting such actions to the FDA, physicians, or the general public.

223. The entire C-Qur Mesh family would have been pulled from the market, undergone further investigations, had additional and more prominent warnings and contraindications, and/or physicians would have been aware of additional risk had Defendants' not violated 21 C.F.R. § 806.01(a)(1).

224. Plaintiff and/or Plaintiff's physician would not have utilized the C-Qur Mesh had Defendants' not violated 21 C.F.R. § 806.01(a)(1).

225. As a direct and proximate result of the Defendants' violation of 21 C.F.R. § 806.01(a)(1), Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## COUNT XIII
## FRAUD

226. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

227. At all relevant times, Defendants' marketed, promoted, and/or sold the C-Qur

Mesh as safe, efficacious, and suitable for human implantation.

228. The C-Qur mesh is not safe, efficacious, or suitable for human implantation.

229. The Defendants' marketed, promoted, and/or sold the C-Qur Mesh as safe, efficacious, and suitable for human implantation with the intent that more patients and physicians would utilize the C-Qur Mesh, increasing the Defendants' profits.

230. Plaintiff and Plaintiff's physician utilized the C-Qur Mesh because they believed the C-Qur mesh was safe, efficacious, and suitable for human implantation at the time, because the Defendant's deceptively marketed, promoted, and/or sold the C-Qur Mesh as such.

231. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed the C-Qur Mesh, and up to the present, knew and willfully deceived Plaintiff, the FDA, Plaintiff's physician, the medical community, and the general public, as to the true facts concerning the C-Qur Mesh, which the Defendants had a duty to disclose.

232. Defendants are the sole bearer of the true, accurate, unaltered information, test, studies, trials, and data on the safety, efficacy, and suitable for human implantation of the C-Qur Mesh, and therefore the Plaintiff and the Plaintiff's doctor had no reason or information to believe that the Defendants claims were in fact false.

233. The Plaintiff and the Plaintiff's physician intended to select a safe and efficacious mesh for hernia and/or soft tissue repair that was suitable for human implantation, and selected the Defendants' C-Qur Mesh because of the false claims that the Defendants made about the safety, efficacy and suitability of the C-Qur Mesh for hernia and/or soft tissue repair as used by the Plaintiff and the Plaintiff's physician.

234. Defendants are the sole bearer of the true, accurate, unaltered information, test, studies, trials, and data on the safety, efficacy, and suitable for human implantation of the C-Qur Mesh, and therefore the Plaintiff and the Plaintiff's physician had no other option but to rely of the Defendants' representations.

235. As a direct and proximate result of Plaintiff's and/or Plaintiff's physicians' \reliance on the Defendants' misrepresentations, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**VICARIOUS LIABILITY**

236. Whenever in this complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendant's officers, agents, servants, employees, or representatives did or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendant or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

**PUNITIVE DAMAGES ALLEGATIONS**

237. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the

alternative, if same be necessary, allege as follows:

238. At all times relevant hereto, Defendants knew or should have known that the Defendants' C-Qur Meshes were inherently more dangerous with respect to the risks of foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

239. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' C-Qur Mesh.

240. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Defendants' C-Qur Mesh.

241. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' C-Qur Meshes cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

242. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' C-Qur Meshes cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of the same.

243. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries caused by the Defendants' C-Qur Mesh.

244. Notwithstanding the foregoing, Defendants continue to aggressively market the Defendants' C-Qur Mesh to consumers, without disclosing the true risk of side effects where there were safer alternatives.

245. Defendants knew of the Defendants' C-Qur Meshes defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' C-Qur Meshes so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Defendants' C-Qur Mesh.

246. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Defendants' C-Qur Meshes in order to ensure continued and increased sales.

247. Defendants' intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using the Defendants' C-Qur Meshes against their benefits.

248. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

249. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant Common Law principles.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,

individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## PRAYER FOR RELIEF

**WHEREFORE,** Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and request compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just a proper as well as:

i. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs, together with interest and costs as provided by law;

ii. Enhanced compensatory damages in an amount to be determined trial;

iii. Reasonable attorneys' fees;

iv. The costs of these proceedings, including past a future cost of the suit incurred herein;

v. All ascertainable economic damages, including past and future loss of earnings and/or earning capacity;

vi. Punitive damages;

vii. Prejudgment interest on all damages as is allowed by law;

viii. Such other and further relief as this Court deems just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

PLAINTIFF RICHARD HEINZ
By his attorneys,

/s/ Adam M. Evans
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*Pro Hac Vice pending*